Exhibit H

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION	Master File Number: 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO: CAROLYN LEWIS, ET AL, VS. ETHICON, INC.	Case Number: 2:12-CV-04301

Videotaped Deposition of

TIMOTHY A. ULATOWSKI

Washington, D.C.

Tuesday, December 17, 2013

9:00 a.m.

Reported by: Laurie Bangart, RPR, CRR

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whether she informed Mrs. Lewis about potential particle loss?
A I don't recall any testimony in regard to that.
Q Do you know whether Dr. Boreham had any knowledge about de novo urinary tract infections and whether she informed Mrs. Lewis about that possibility?
A Let me look at her testimony, at least what I extracted.
I haven't referenced that in my report.
Q You cite the current updated FDA website in your report on SUI that was out in March, I believe; correct?
A Right.
Q And you would agree that the FDA's website says that the information they reviewed is limited in outcomes after one year; correct?
MS. SUTHERLAND: Objection.
If you've got the document, you want to show him?
BY MR. KUNTZ:
Q Well, you have it cited in your report, don't you?
MS. SUTHERLAND: That doesn't mean

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he's got it memorized, Jeff.
MR. KUNTZ: Maybe if he would have brought some stuff, we could have it here.
(Exhibit 11 was marked for identification.)
BY MR. KUNTZ:
Q I'm handing you what's going to be marked Plaintiff's Exhibit 11.
A Okay.
I'll put this away, this other away.
Q Do you recognize that document? Have you seen that before, Mr. Ulatowski?
A Yes.
Q And I think in your report -- the first bullet point is something that you have in your report, and you underline it.
You would agree with me safety and effectiveness of multi-incision slings is well established in clinical trials that followed patients for up to one year?
A That's what FDA stated.
Q So they're not relying on any data or making that statement for anything over one year; correct?
MS. SUTHERLAND: Objection.
THE WITNESS: Well, that's a

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blanket -- this is for all TVT devices, so they're going to be commenting as a group. Of course there's longer term studies for various other, various types of TVT devices.
BY MR. KUNTZ:
Q You don't have any opinions in this case as to whether the TVT IFU adequately discloses adverse reactions; correct?
A Well, I have an opinion about the adequacy of the labeling in regard to regulatory requirements, and I deferred on specifics regarding adverse effects to medical opinion, which is required, I think, in regard to assessing adverse effects.
Q So you would agree with me that you have no opinion as to the whether TVT IFU adequately discloses adverse reactions? You agree with that?
A Not beyond the fact that it meets the regulatory requirements for labeling, but as far as the ingredients of the adverse effects section, that I would defer to medical opinion.
Q And you have no opinion on this in this case whether Medical Affairs at Ethicon was aware of significant adverse reactions?
MS. SUTHERLAND: Objection.
THE WITNESS: I guess I don't

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understand that question. Could you repeat it, please.
BY MR. KUNTZ:
Q Do you have any opinion in this case whether Medical Affairs at Ethicon was aware of significant adverse reactions or not?
A Well, there were MDR reports. They would have been aware of those MDR reports.
Q Do you know, according to the MDR reports you discussed in your report, what adverse reactions they would have been aware of?
A There were various medical outcomes, adverse effects reported in the -- as documented in the issue report, so -- and it spans what's in the labeling. So they knew of those. Of course, they would know of those MDR reports. They commented on those.
Q These are what you discuss on page 59 of your report?
A Yes.
Q So you believe that Medical Affairs was aware of all of these adverse reactions; is that true?
A Well, I think first of all that Ethicon, since it's in the issue reports, would have been aware of these.
Q So they would have been aware of hematomas?

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MS. SUTHERLAND: Did you finish your answer? I thought he might have cut you off.
BY MR. KUNTZ:
Q I'm sorry if I did.
A No. I'm commenting on here what are in the issue reports.
Q That would include hematomas?
A I've listed that, yes.
Q Exposure?
A Yes.
Q I take it that's a typo, double exposure.
A Oh, yeah, mm-hmm.
Q Exposure.
Pain?
A Yes.
Q Bleeding?
A Mm-hmm.
Q Retention? I assume you mean urinary retention.
A Right.
Q Erosion?
A Mm-hmm.
Q Voiding issues?
A Yes.

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Q Infection?
A Yes.
Q Fistulas?
A Yes.
Q Nerve issues?
A Yes.
Q And then skipping down, procedural errors?
A Yes.
Q Malfunctions?
A Yes.
Q Other voiding problems?
A Yes.
Q And you'd also agree that they're aware of shrinkage?
A Yes.
Q Tissue reaction and scarring?
A Yes. Rare reports of those.
Q Is there any reason that you only reviewed the issue reports from January 1, 1999 to December 31, 2000?
A Well, I had those reports. I've reviewed a lot of issue reports for a lot of products. I think for the TVT products, I've got thousands of other issue reports for TVT products as a whole, but for retropubic, no, I don't recall why that was selected

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offhand. I don't recall.
Q But you can agree with me that for the TVT retropubic, you only reviewed, what is that; two years of issue reports?
A That's correct. For this particular report, that's what I had.
Q Do you agree with me that you don't have an opinion on the accuracy or completeness of the adverse reactions section in the IFU?
A Yeah, that goes hand in hand with my other comment that I think that requires medical opinion as to what should be included there.
Q The answer to my question is yes, you would agree with me?
A Yes.
Q And you'd agree with me that you don't have an opinion as to whether the TVT IFU adequately disclosed the risks known to medical affairs?
A Repeat that, please.
Q You don't have an opinion as to whether the TVT IFU adequately disclosed the risks known to medical affairs?
A Yeah, I think that's subject to the deposition testimony, their interpretation of events and what they believe to be significant and reportable

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in the IFU.
Q And you have no opinion as to what adverse reactions should be in the patient brochure?
A That's correct. I think that requires medical opinions to assess that.
Q Have you reviewed the 2012 patient brochure in this case?
A I believe so. I've got them all listed, what I looked at. At least I think so. Let me turn back to that.
Now, you said the IFU?
Q No. 2012 patient brochure.
A Oh, patient brochure. You'd have to give me a Bates number on that. I don't think I put a date on it.
Q Here's a copy of it.
A I think I reviewed all of them, but a specific one I'll have to see.
(Exhibit 12 was marked for identification.)
BY MR. KUNTZ:
Q Handing you what's been marked Plaintiff's Exhibit 12.
Do you recognize that document as the 2012 patient brochure?